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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,481	06/20/2001	Takao Hamakubo	P21128	9557

7055 7590 12/02/2003

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,481

Applicant(s)

HAMAKUBO ET AL.

Examiner

Shanon Foley

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

In the paper submitted October 17, 2003, applicant amended claim 1. Upon reconsideration of the claims, the discussion at the interview and the arguments presented in the response, it is determined that new grounds of rejection are required.

Election/Restrictions

Upon reconsideration of the restriction between the various proteins listed in claims, it is determined that the restriction is withdrawn between the various proteins. The restriction of groups II-VI remains in effect. Therefore, claims 9-14 remain withdrawn from consideration due to nonelected subject matter and claims 1-8 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method for preparing a protein, but does not contain any method steps to prepare the protein. The steps only conclude in separating a recombinant baculovirus. To obviate this rejection, it is suggested that applicant append a step that includes separating the protein from the budded baculovirus. However, if applicant amends claim 1 to recite this step, the methods steps of amended claim 1 would be indistinguishable from the steps of claim 2. In addition, it cannot be determined what a "substrate of the membrane-bound enzyme", "a membrane-bound enzyme activator" or a "protein involved in formation of high dimensional

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structure of a protein" is. Also, it appears that a "protein involved in antigen presentation" could be the antigen itself, but it is not clear. This rejection also affects claims 2-8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Loisel et al.

(Nature Biotechnology, Nov. 1997; 15: 1300-1304).

The claims are drawn to a method for preparing a protein by culturing an insect host cell infected with at least one recombinant baculovirus that encodes the protein, expressing the protein in a budded baculovirus released from the host cell, separating the budded baculovirus and recovering the protein expressed by the baculovirus.

Loisel et al. teach preparing functional β_2 -adrenergic receptors by infecting insect Sf9 cells with recombinant baculovirus, expressing the receptor from budded baculovirus, separating the budded virus and recovering the receptors, see "Experimental protocol" on pages 1303-1304 and Figures 3-6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Possee (Current Opinion in Biotechnology, 1997; 8: 569-572) and either Grabherr et al. (Biotechniques, 1997; 22 (4): 730-735) or Boublik et al. (Biotechnology, Oct. 1995; 13: 1079-1084).

See the summary of the claims above.

Grabherr et al. express the ectodomain of the HIV-1 gp41 envelope protein on the surface of baculovirus. Grabherr et al. infect Sf9 cells with recombinant virus, expressing the glycoprotein in budded virus, separating the budded virus from cell culture, confirming the presence of envelope protein on the surface of the virus by ELISA and analyzing the protein expressed by Western blot analysis, see the second full paragraph on page 732 to the last paragraph on page 735.

Boublik et al. teach infecting insect cells Sf9 cells with a recombinant baculovirus expressing HIV-1 gp120. Boublik et al. separate the virus and analyzes the recombinant protein by Western blot analysis, see "Display of a large complex glycoprotein, HIV-1 gp120" on page 1082, Figure 7 and the next to the last paragraph on page 1083.

Neither Grabherr et al. nor Boublik et al. teach expressing any of the various proteins recited in the claims. However, one of ordinary skill in the art at the time the invention was made would have been motivated to express and purify any class of protein from the surface of a baculovirus to produce complex structures and/or native conformational mammalian proteins. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing membrane or structural proteins in a baculovirus because Grabherr et al. or Boublik et al. express and purify foreign proteins from baculovirus and Possee concludes that any protein can be expressed and displayed on the baculovirus surface, see

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“Advances in virion display technology” on page 570 and the conclusion on page 571.

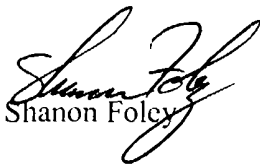
Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Shanon Foley